

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GUARDANT HEALTH, INC.,
Petitioner,

v.

UNIVERSITY OF WASHINGTON,
Patent Owner.

IPR2022-00449
Patent 10,689,699 B2

Before JOHN G. NEW, ZHENYU YANG, and TINA E. HULSE,
Administrative Patent Judges.

YANG, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. §§ 314(a), 325(d)

I. INTRODUCTION

Guardant Health, Inc. (“Petitioner”) filed a Petition (Paper 3 (“Pet.”)), seeking an *inter partes* review of claims 1–27 of U.S. Patent No. 10,689,699 B2 (Ex. 1001, “the ’699 Patent”). University of Washington (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). With our authorization (Ex. 3001), Petitioner filed a Reply (Paper 11), and Patent Owner filed a Sur-reply (Paper 12).

For the reasons provided below, we exercise our discretion under 35 U.S.C. § 325(d), and deny institution of an *inter partes* review.

A. Related Matters

According to the parties, the ’699 patent is asserted against Petitioner in *TwinStrand Biosciences, Inc. et al. v. Guardant Health, Inc.*, 1-21-cv01126 (D. Del.). Pet. 13; Paper 5, 1.

Petitioner also filed a petition in IPR2022-00450, challenging the same claims of the ’699 patent. In a concurrently issued decision, we deny that petition. IPR2022-00450, Paper 13.

B. The ’699 Patent and Related Background

The ’699 patent relates to methods of lowering the error rate of massively parallel DNA sequencing using duplex consensus sequencing. Ex. 1001, code (54), 17:57–59.

The ’699 patent states massively parallel DNA sequencing “offer[ed] the unique ability to detect minor variants within heterogeneous mixtures.” *Id.* at 1:31–40. It notes the rapid development of clinical applications of deep sequencing in “prenatal screening for fetal aneuploidy, early detection of cancer and monitoring its response to therapy with nucleic acid-based serum

biomarkers.” *Id.* at 1:41–48 (internal citations omitted). Deep sequencing, however, according to the ’699 patent, had limitations, including “a practical limit of detection . . . imposed by errors introduced during sample preparation and sequencing,” resulting in “approximately 1% of bases [being] incorrectly identified.” *Id.* at 1:59–2:6. The ’699 patent states “[t]his background level of artifactual heterogeneity establishes a limit below which the presence of true rare variants is obscured.” *Id.* at 2:7–9.

The ’699 patent acknowledges several attempts aimed at improving the accuracy and sensitivity of sequencing:

For example[,] techniques whereby DNA fragments to be sequenced are each uniquely tagged prior to amplification have been reported. Because all amplicons derived from a particular starting molecule will bear its specific tag, any variation in the sequence or copy number of identically tagged sequencing reads can be discounted as technical error. This approach has been used to improve counting accuracy of DNA and RNA templates and to correct base errors arising during PCR or sequencing. Kinde et. al. reported a reduction in error frequency of approximately 20-fold with a tagging method that is based on labeling single-stranded DNA fragments with a primer containing a 14 bp degenerate sequence. This allowed for an observed mutation frequency of ~0.001% mutations/bp in normal human genomic DNA.

Id. at 2:10–31 (footnote added, internal citations omitted). But, because “true mutation frequency in normal cells is likely to be far lower,” the ’699 patent reasons that “the mutations seen in normal human genomic DNA by Kinde et al. [still] are likely the result of significant technical artifacts.” *Id.* at 2:32–38.

The ’699 patent states “[i]t would be desirable to develop an approach for tag-based error correction.” *Id.* at 2:63–64. According to the ’699 patent,

its approach “reduces or eliminates artifactual mutations arising from DNA damage, PCR errors, and sequencing errors; allows rare variants in heterogeneous populations to be detected with unprecedented sensitivity; and . . . capitalizes on the redundant information stored in complexed double-stranded DNA.” *Id.* at 2:64–3:2.

C. Illustrative Claims

Among the challenged claims, claims 1 and 20 are independent. They are illustrative of the claimed subject matter and are reproduced below.

1. A method, comprising:

- a) providing a population of circulating DNA molecules obtained from a bodily sample from a subject;
- b) converting the population of circulating DNA molecules into a population of non-uniquely tagged parent polynucleotides, wherein each of the non-uniquely tagged parent polynucleotides comprises (i) a sequence from a circulating DNA molecule of the population of circulating DNA molecules, and (ii) an identifier sequence comprising one or more polynucleotide barcodes, such that each non-uniquely tagged parent polynucleotide is substantially unique with respect to other non-uniquely tagged parent polynucleotides in the population;
- c) amplifying the population of non-uniquely tagged parent polynucleotides to produce a corresponding population of amplified progeny polynucleotides;
- d) sequencing at least a portion of the population of amplified progeny polynucleotides to produce a set of sequence reads;
- e) grouping the sequence reads into families, each of the families comprising sequence reads comprising the same identifier sequence and having the same start and stop positions, whereby each of the families comprises sequence

reads amplified from the same non-uniquely tagged parent polynucleotide; and

f) collapsing sequence reads in each family to yield a base call for each family corresponding to one or more genetic loci.

Ex. 1001, 37:46–38:51.

20. A method, comprising:

a) attaching a set of molecular tags to a population of circulating DNA molecules obtained from a bodily sample of a subject to produce a population of tagged original DNA molecules, wherein a plurality of the tagged original DNA molecules has identical molecular tags, and wherein each tagged original DNA molecule is substantially unique with respect to other tagged original DNA molecules in the population;

b) amplifying the population of tagged original DNA molecules to produce a corresponding population of DNA molecule amplicons;

c) sequencing at least a portion of the population of DNA molecule amplicons to produce a set of sequence reads;

d) grouping the sequence reads into families based on i) the molecular tag and ii) sequence information derived from the circulating DNA molecule, whereby each of the families comprises sequence reads amplified from the same tagged original DNA molecule; and

e) collapsing sequence reads in each family to provide an error-corrected consensus sequence read for each family corresponding to one or more genetic loci.¹

Id. at 40:12–32.

¹ We incorporate the Certificate of Correction (Ex. 3002) to correct certain typographic errors in claim 20.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claims Challenged	35 U.S.C. §²	Reference(s)
1–17, 20–27	102	Talasaz ³
1–17, 20–27	103	Talasaz
18, 19	103	Talasaz, Eltoukhy ⁴

Petitioner relies on the declaration of John Quackenbush, Ph.D., as support for its Petition. Ex. 1002.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2020). Under that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner states that no claim term needs to be construed for this proceeding. Pet. 14. It nevertheless discusses the term “circulating DNA molecules” to “provide[] context for understanding the scope of the term.”

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102, 103, effective March 16, 2013. As explained below, we deny institution under § 325(d), regardless of which version of the law applies.

³ U.S. Patent No. 9,834,822, issued Dec. 5, 2017 (Ex. 1028, “Talasaz”).

⁴ U.S. Patent No. 9,920,366, issued Mar. 20, 2018 (Ex. 1035, “Eltoukhy”).

Id. Petitioner observes that the term is not used in the specification of the '699 patent. *Id.* at 15. Citing “[s]tatements made by Patent Owner during prosecution of a related case” (Ex. 1005, 183), Petitioner argues that “[cfDNA] cell-free DNA is encompassed by the broader term ‘circulating DNA molecules.’” *Id.*

Patent Owner contends that Petitioner’s “unofficial claim construction” is incomplete and incorrect. Prelim. Resp. 5–9. According to Patent Owner, Petitioner is wrong in treating the term “circulating DNA molecules” as coextensive with cfDNA because “not all cell-free DNA is circulating.” *Id.* at 6–9; *see also* Sur-reply 1 (“There are many sources of cfDNA that are not circulating.”). Patent Owner, however, does not dispute that circulating cfDNA is encompassed by the term “circulating DNA molecules.” Prelim. Resp. 7–8.

Based on the arguments and evidence presented, we determine “circulating DNA molecules” include cfDNA circulating in plasma and serum. *See* Ex. 1005, 180–84. This determination as to the scope of “circulating DNA molecules” is sufficient for purposes of this Decision, and we need not further address the term at this time.

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to expressly construe any other claim term.

B. Analysis

Petitioner contends that Talasaz anticipates and renders obvious claims 1–17 and 20–27 of the '699 patent. Pet. 31–57. Petitioner also

contends that the combined teachings of Talasaz and Eltoukhy render obvious claims 18 and 19. *Id.* at 57–62.

The '699 patent issued from application No. 16/411,066 (“the '066 application”), filed May 13, 2019, which is a continuation of application No. 15/660,785 (“the '785 application”), filed July 26, 2017, which in turn, claims priority to several other applications. Ex. 1001, codes (21), (22), (60), (63). Both Talasaz and Eltoukhy are U.S. patents issued after July 26, 2017, the filing date of the '785 application. *See* Ex. 1028, code (45); Ex. 1035, code (45). Nevertheless, Petitioner asserts that Talasaz and Eltoukhy qualify as prior art because the challenged claims “are not entitled to priority earlier than the May 13, 2019 filing date of the '066 application.” Pet. 16, 31.

Specifically, Petitioner argues that the '785 application lacks written description support for “converting” or “attaching” tags to “circulating DNA molecules,” as recited in independent claims 1 and 20. *Id.* at 17–30. Patent Owner argues that we should deny institution under § 325(d) “because the Office already found that the specification provides § 112 support for tagging circulating DNA.” Prelim. Resp. 10. For the reasons explained below, we find Patent Owner’s arguments persuasive.⁵

⁵ As another basis for its priority arguments, Petitioner contends that the '785 application does not enable methods for “converting” or “attaching” tags to “circulating DNA molecules.” Pet. 30. Patent Owner asserts that “[t]he Petition gives enablement only cursory treatment.” Prelim. Resp. 36. We agree with Patent Owner. Petitioner disposes of the entire enablement argument in a single seven-line paragraph. *See* Pet. 30. It provides no meaningful analyses of the factors set forth in *In re Wands*, 858 F.2d 731,

Institution of an *inter partes* review is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (explaining that because § 314 includes no mandate to institute review, “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion”); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (stating that under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding”).

Under § 325(d), in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” Our § 325(d) analysis employs a two-prong framework: (1) whether the arguments presented in the petition are the same or substantially the same as those previously presented to the Office; and (2) if so, whether the petitioner has demonstrated a material error by the Office in its prior consideration of those arguments. *Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (“*Advanced Bionics*”), 8 (PTAB Feb. 13, 2020) (precedential). When analyzing the second prong, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at 9. “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.*

737 (Fed. Cir. 1988). *See id.* We find these two sentences of conclusory statements inadequate to show lack of enablement of the challenged claims.

1. The Sibling Application

Patent Owner asserts that “the Examiner already considered Petitioner’s exact arguments in the context of a sibling application and found written description support.” Prelim. Resp. 10. The “sibling application” that Patent Owner refers to is application No. 16/411,045 “the ’045 application”), which issued as U.S. Patent No. 10,604,804. Ex. 1004. Both the ’066 application, which issued as the ’699 patent, and the ’045 application are continuation applications of the ’785 application. Ex. 1001, code (63); Ex. 1004, code (63). These applications contain the same specification and were examined by the same examiner at the same time. *See* Ex. 1001, cover; Ex. 1004, cover (identifying David C. Thomas as the primary examiner).

Patent Owner contends that “the portions of the claim language that forms the basis for Petitioner’s written description challenge here is identical to the portions of the claim language that formed the basis for the examiner’s written description rejection in the ’045 Application,” except the challenged claims require “circulating DNA molecules,” whereas the claims in the ’045 application recite “circulating nucleic acid molecules.” Prelim. Resp. 11 n.1, 12. Petitioner does not address this contention in its Reply.

2. Prosecution History of the ’045 Application

During the prosecution of the ’045 application, the examiner rejected the then-pending claims for “failing to comply with the written description requirement.” Ex. 1005, 148. According to the examiner, the specification contains no disclosure of “providing a plurality of circulating nucleic acid molecules obtained from a bodily sample of the subject” and “attaching tags to generate non-uniquely tagged parent polynucleotides.” *Id.* at 149.

Thereafter, the applicant initiated an interview with the examiner. *Id.* at 170. According to the examiner, during the interview,

In response to the rejections under 35 U.S.C. 112, first and second paragraph rejections, Applicant's agent further explained and described the sources of the claimed circulating nucleic acid molecules and pointed to support in the specification of these sources, and also explained the distinction of uniquely and non-uniquely tagged polynucleotides, and also pointed to paragraphs and figures in the disclosure that support these terms. The examiner indicated that these explanations and arguments may be sufficient, with or without claim[] amendments, to overcome the rejections.

Id.

The applicant also addressed the rejection for lack of written description support in the response to the office action. *Id.* at 179–89. Specifically, the applicant pointed to paragraphs 4 and 84 of the as-filed specification. *Id.* at 181–83. According to the applicant, paragraph 84 discloses methods of using barcode sequences for “a large number of applications,” including accurate detection of altered genomic copy number (e.g., for sensitive diagnosis of genetic conditions such as trisomy 21), quantification of circulating microRNAs, and quantification of viral load of DNA or RNA viruses. *Id.* at 181. The applicant argued that “one of ordinary skill in the art would recognize each of those example applications to include, inter alia, ‘providing a plurality of circulating nucleic acid molecules obtained from a bodily sample of the subject,’” as recited in the pending claims. *Id.* The applicant noted that one of the references cited in paragraph 84 is entitled “Noninvasive detection of fetal trisomy 21 by sequencing of DNA in maternal blood: a study in a clinical setting.” *Id.* According to the applicant, that reference “was incorporated by reference in

its entirety in the specification and is a further clear example of the use of the claimed method with samples of circulating DNA.” *Id.*

The applicant further argued that paragraph 4 provides additional support for “circulating nucleic acid molecules.” *Id.* Specifically, the applicant pointed out that, paragraph 4 discloses applications for analyzing cell-free nucleic acid molecules, including prenatal screening for fetal aneuploidy, early detection of cancer and monitoring its response to therapy with nucleic acid-based serum biomarkers. *Id.*

The applicant emphasized that

Nowhere does the disclosure of the as-filed specification limit or restrict the source or nature of the provided nucleic acid molecules for *any* embodiment described therein. In fact, many of the applications for sequencing cell-free nucleic acid recited in paragraph [0004], are expressly considered in the detailed description of the application as-filed and at least at paragraph [0084].

Id. at 182–83; *see also id.* at 183 (quoting paragraph 72 of the as-filed specification for stating that “any double stranded target nucleic acid molecule may be ligated to an SMI adaptor molecule ...”). Based on these disclosures, the applicant concluded that “the as-filed specification fully describes and provides adequate written description” for “a plurality of circulating nucleic acid molecules obtained from a bodily sample of the subject.” *Id.* at 185.

With regard to “attaching tags to generate non-uniquely tagged parent polynucleotides,” the applicant contended that although some embodiments use distinct barcode sequences as tags, “the specification is very clear throughout that this is not a requirement.” *Id.* at 186. The applicant asserted that paragraph 26 teaches that “nucleotide n-mer sequences may be any

suitable length to produce a sufficiently large number of unique tags” with distinct tag sequences. *Id.* at 186–87. According to the applicant, the “uniqueness” of the tag “refers to the distinct tag sequence when compared to other tags in the set of tags to be used to label nucleic acid fragments.” *Id.* at 187.

The applicant pointed to paragraph 26 for stating that “each n-mer sequence may, in some embodiments, be between 3 to 20 nucleotides in length.” *Id.* The applicant contended that

[O]ne of ordinary skill in the art would understand that a 3 nucleotide SMI n-mer sequence would only generate 4^3 (64) distinct tag sequences (if fully degenerate) and as little as 2^3 (8) distinct tag sequences (if semi-degenerate). Even if a 3 nucleotide fully degenerate SMI n-mer sequence is ligated to each end of a target nucleic acid molecule, only 4^6 (4,096) distinct tag sequences (after the attachment step) would be generated. . . . [T]hese examples and many more within the range of 3 to 20 nucleotides of degenerate or semi-degenerate nucleotide n-mer sequences would comprise a plurality of distinct barcode sequences and reasonably can be used to generate non-uniquely tagged parent polynucleotides (e.g., some circulating nucleic acid molecules are tagged with the same distinct barcode sequence because, for example, distinct barcode sequences are present in a number less than the number of circulating nucleic acid molecules provided in the bodily sample).

Id.

The applicant also pointed to paragraph 38 for disclosing that “[a] hybrid method using a combination of sheared ends and shorter n-mer tag (such as 1 or 2 or 3 or 4 or more degenerate or semi-degenerate bases) in the adapter may also serve as unique molecular identifiers.” *Id.* at 188. The applicant further argued that “Figure 3 provides express support” for

“attaching tags to generate non-uniquely tagged parent polynucleotides.” *Id.* Thus, according to the applicant, “the specification clearly supports non-uniquely tagging polynucleotides by attaching tags comprising barcode sequences (that are distinct from each other) such that each distinct barcode sequence may be used to label more than one parent polynucleotide.” *Id.*

Thereafter, upon finding the applicant’s evidence and arguments overcame the written-description-support rejection, the examiner allowed the claims. *Id.* at 409, 413. In the Reasons for Allowance, the examiner stated:

Applicant has pointed to specific portions of the specification that describe providing a plurality of circulating nucleic acid molecules obtained from a bodily sample of the subject, particularly with regard to quantifying single nucleotide variant cancer biomarkers in circulating nucleic acids, and attaching tags to generate non-uniquely tagged parent polynucleotides. Therefore, the claims do not comprise new matter, and furthermore, it is now clear how non-uniquely tagged parent polynucleotides are generated from a pool of distinct barcode sequences.

Id. at 414.

3. Same or Substantially the Same Arguments

In the instant proceeding, Petitioner contends that the ’785 application “lacks descriptive support for ‘converting’ or ‘attaching’ tags to ‘circulating DNA molecules.’” Pet. 18. Specifically, Petitioner argues that the ’785 application “does not describe methods for ‘circulating DNA molecules’ or cfDNA, or even mention those terms.” *Id.* Petitioner also asserts that the ’785 application does not describe “‘converting’ or ‘attaching’ tags to circulating DNA to generate ‘non-uniquely tagged parent

polynucleotides’ or ‘original DNA molecules’ bearing ‘identical molecular tags.’” *Id.* at 19.

Patent Owner argues that “Petitioner’s written description and enablement challenges [are] the nearly identical § 112 rejections that Patent Owner overcame during prosecution of [the] related [’045] application.” Prelim. Resp. 11. We find Patent Owner’s argument persuasive.

During the prosecution of the ’045 application, the examiner rejected the then-pending claims on the basis that the specification does not provide sufficient written description support for “providing a plurality of circulating nucleic acid molecules obtained from a bodily sample of the subject” and “attaching tags to generate non-uniquely tagged parent polynucleotides.” Ex. 1005, 148–49.

As explained above, the ’785 application and its two continuation applications (the ’045 application, and the ’066 application, which issued as the ’699 patent) contain the same specification and were examined by the same primary examiner. *See supra* Section II.B.1. In addition, the claim language challenged here is the same in scope as that rejected in the ’045 application, except the challenged claims require “circulating DNA molecules,” whereas the claims in the ’045 application recite “circulating nucleic acid molecules.” *Id.*

Based on this record, we find Petitioner’s arguments challenging written description support are the same or substantially the same as those considered by the examiner during the prosecution of the ’045 application.

4. Material Error

Having found that the condition in the first part of the two-prong framework is satisfied, we next evaluate whether Petitioner has demonstrated a material error by the Office in its prior consideration of those arguments. *Advanced Bionics*, 8. Based on the current record, we determine Petitioner has not met its burden to show the examiner materially erred.

Petitioner contends that “there is no indication that the Examiner critically evaluated priority support for the claimed ‘circulating DNA’ (or any other aspect of the current claims).” Pet. 63 (“The prosecution history does not indicate that the Examiner critically evaluated the ’699 patent claims for section 112 support in the priority documents.”).

It is true that the examiner did not reject claims of the ’066 application for failing to comply with the written description requirement. *See* Ex. 1006, 433–44 (rejecting claims for double patenting and indefiniteness). As explained above, however, the same examiner, when examining the copending ’045 application at the same time when the ’066 application was being examined, rejected claims for the same reason Petitioner now asserts in this proceeding. *See supra* Sections II.B.2, II.B.3; *see also* Ex. 1005, 148–49 (stating the specification does not provide written description support for “circulating nucleic acid molecules” and “attaching tags to generate non-uniquely tagged parent polynucleotides”).

After the applicant initiated an interview and filed a response, the examiner allowed the claims in the ’045 application in November 2019. Ex. 1005, 409. The examiner explained that the applicant “pointed to specific portions of the specification,” which was sufficient to overcome the

rejections under § 112. *Id.* at 414. We are not persuaded that the examiner did not “critically evaluate[] priority support” for the challenged claims (Pet. 63), merely because he did not repeat the same rejection in the ’066 application examination a month later.⁶ *See* Ex. 1006, 433 (mailing the office action in December 2019).

As Patent Owner argues and Petitioner does not dispute, the claim language challenged here is the same in scope as that rejected in the ’045 application, except the challenged claims require “circulating DNA molecules,” whereas the claims in the ’045 application recite “circulating nucleic acid molecules.” Prelim. Resp. 11–12.

In its Reply, Petitioner points out that the Reasons for Allowance in the ’045 application “does not mention DNA at all.” Reply 2 (citing Ex. 1005, 414). Thus, Petitioner contends that “[t]he ’045 Examiner never found support for ‘circulating DNA’ OR ‘cfDNA.’” *Id.* According to Petitioner, “[p]resumably, the Examiner relied on the ‘circulating microRNAs’ in ¶[0084] and Mitchell (Ref#11) cited in ¶[0004]. MicroRNAs might be relevant to ‘circulating nucleic acid molecules’ of the ’045 application claims but are not ‘circulating DNA molecules.’” *Id.* We are not persuaded.

⁶ The examiner rejected the pending claims in the ’066 application “under the judicially created doctrine of obviousness-type double patenting” as being unpatentable over the allowed claims of the ’045 application. Ex. 1006, 436–38. This further confirms that the examiner was cognizant of the ’045 application prosecution when rejecting the claims in the ’066 application.

As a preliminary matter, we agree with Patent Owner that Petitioner's presumption is merely speculation, and not evidence. *See* Sur-reply 6–7. Moreover, during the prosecution of the '045 application, in the response to the written-description-support rejection, the applicant explained that circulating nucleic acids comprise both cfDNA and cfRNA. Ex. 1005, 184; *see also* Sur-reply 7 (“The genus of ‘circulating nucleic acids’ can only include circulating RNA and DNA.”). The written description must lead an ordinarily skilled artisan to understand that an inventor possessed the entire scope of the claimed invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc). Petitioner does not point to any evidence to show that when the examiner found written description support for “circulating nucleic acids,” he did so for circulating RNA only.

Petitioner has not presented competent evidence or persuasive arguments to show that the examiner materially erred in finding written description support for “circulating nucleic acid molecules” and “attaching tags to generate non-uniquely tagged parent polynucleotides.”

5. Summary

In sum, the lack-of-written-description-support arguments presented in the Petition are same or substantially the same as those the examiner considered during prosecution of the '045 application. Petitioner has not demonstrated that the Examiner materially erred in that consideration.

III. CONCLUSION

Petitioner's anticipation and obviousness grounds rest on the priority date of the challenged claims. Because we decline to reconsider Petitioner's challenge of priority date based on lack of written description support, we

exercise our discretion under § 325(d) and decline to institute *inter partes* review of the '699 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:
ORDERED that the Petition is denied.

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